

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Trang T. Le et al.)	GROUP ART UNIT:	1615
SERIAL NO.:	09/932,494)	CONFIRMATION NO.:	5208
EXAMINER:	Susan T. Tran)	ATTORNEY DOCKET	C-3320/1/US
FILED:	August 17, 2001)	NO.:	(PC31245)
TITLE:	ORAL FAST-MELT FORMULATION OF A CYCLOOXYGENASE-2 INHIBITOR			

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

August 11, 2006

RESPONSE TO OFFICE ACTION

Sir:

In response to the Office action of February 14, 2006, the time for response to which has been extended by three months, please consider the following remarks.

Claims 1-3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-89, and 95-100 are currently pending. All pending claims stand rejected under 35 U.S.C. §103(a) as being unpatentable over Mizumoto et al., U.S. Patent No. 5,576,014 ("Mizumoto") in view of Straub et al., U.S. 6,395,300 ("Straub"), and as being unpatentable over Mizumoto in view of Straub and Jain et al., U.S. Patent No. 6,316,029 ("Jain"). Reconsideration of these rejections is respectfully requested.

Straub describes formulations of low solubility drugs in a porous matrix wherein the dissolution rate of the drug is enhanced when the matrix is contacted with an aqueous medium. Straub names at least 45 categories of drugs (see col. 4, line 22 through col. 7, line 20) contemplated for use in his compositions. Over 410 drugs are identified by name; one of these is celecoxib. Straub names over 100 drugs as preferred (see col. 7, line 45 through col. 8, line 9). Celecoxib is one of these drugs.

Applicants respectfully assert that the Office has not established a *prima facie* case of obviousness, because the Office has not shown any suggestion or motivation to combine Mizumoto and Straub to arrive at, for example, the composition of claim 1. Nothing in Straub or Mizumoto or the knowledge generally available to one of ordinary skill in the art would have led

one of skill in the art to select celecoxib from the **more than 410 drugs** identified by Straub, to combine celecoxib with one of the wetting agents or surfactants mentioned by Straub, and to prepare a composition as taught by Mizumoto comprising celecoxib and Straub's wetting agent or surfactant. That is, nothing in Straub or Mizumoto or the general knowledge would have suggested the *desirability*, and thus the obviousness, of combining the teachings of Mizumoto and Straub, see In re Fulton, 391 F.3d 1195, 1200-01 (Fed. Cir. 2004). While it is true that Strab indicated that celecoxib is a preferred drug, more than 99 other drugs are likewise identified as being preferred. None of Straub's examples comprise celecoxib, and there is no indication whatsoever that celecoxib is particularly preferred. Contrary to the Office's suggestion, Straub does not specifically teach processing celecoxib with an excipient such as a wetting agent or surfactant. Rather, Straub mentions that wetting agents may in general be used to facilitate dissolution, but does not suggest the specific combination of celecoxib with a wetting agent or surfactant.

Likewise, the Office has not established a *prima facie* case of obviousness, because the Office has not shown any suggestion or motivation to combine Mizumoto, Straub, and Jain. Nothing in any of these three references, or the general knowledge, would have motivated one of skill in the art to select celecoxib from the more than 410 other drugs mentioned by Straub, to combine celecoxib with one of the wetting agents or surfactants mentioned by Straub or Jain, and to prepare a composition as taught by Mizumoto comprising celecoxib and Straub's or Jain's wetting agent or surfactant. Nothing in any of the three references or the general knowledge would have suggested the desirability of such a combination. Indeed, the desirability of this combination was suggested for the first time by the instant application.

For the foregoing reasons, the Applicants submit that the present invention is now in condition for allowance. Early allowance of all pending claims is respectfully solicited.

Respectfully submitted,



Patricia K. Fitzsimmons
Registration No. 52,894

Pharmacia Corporation
Post Office Box 1027
St. Louis, MO 63006
Telephone: 314.274.1490
Facsimile: 314.274.9095